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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,199	11/26/2003	Ann Fruhling	U0585.10.U	9044

42640 7590 10/01/2007
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EXAMINER

KIM, PAUL

ART UNIT	PAPER NUMBER
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2161

MAIL DATE	DELIVERY MODE
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10/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/723,199	Applicant(s) FRUHLING ET AL.	
	Examiner Paul Kim	Art Unit 2161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-22, 24, 27-31, 34, 35, 39-41, 46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-22, 24, 27-31, 34, 35, 39-41, 46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This Office action is responsive to the following communication: Amendment filed on 21 September 2007.
2. Claims 17-22, 24, 27-31, 34-35, 37, 39-41 and 46-47 are pending and present for examination.

Continued Examination Under 37 CFR 1.114

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 September 2007 has been entered.

Response to Amendment

4. Claims 17, 21, 30, and 34 have been amended.
5. No claims have been added.
6. Claims 1-16, 19, 23, 25-26, 32-33, 36, 38, and 42-45 have been cancelled.

Claim Rejections - 35 USC § 101

7. As per the rejection under 35 U.S.C. 101, Applicant's Amendment has been acknowledged. Accordingly, the rejection has been withdrawn.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **Claims 17, 30, and 46-47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Jamroga et al (U.S. Patent No. 6,574,742), hereinafter referred to as JAMROGA, filed on 10 November 2000, and issued on 3 June 2003, in view of Cusack et al (U.S. Patent No. 6,493,724, hereinafter referred to as CUSACK), filed on 19 June 2000, and issued on 10 December 2002.

10. **As per independent claims 17 and 30**, JAMROGA, in combination with CUSACK, discloses:

A method for managing specimen data reporting among specimen collection facilities, said method comprising:

receiving a specimen report from a client terminal {See JAMROGA, C7:L11-14, wherein this reads over "[b]y 'participant institution' is meant hospitals, radiology group practices, physician group practices, medical image centers, and other healthcare facilities and organizations"}, wherein the specimen report comprises a specimen description including specimen image content {See JAMROGA, C9:L23-34, wherein this reads over "[e]ach set of delivery instructions and accompanying data on database is stored and retrievable under a unique identifier or identifiers. The identifiers comprise an identification of the particular instruction set for the names participant institution"};

processing the specimen report in accordance with a facility identifier corresponding to the specimen collection facility at which the client terminal is located {See JAMROGA, C9:L48-59, wherein this reads over "the proxy server upon acceptance of delivery instructions automatically calculates the particular instruction sets as initial data received. Upon calculation that the requested transaction is a storage request the proxy server calculates and associates a digital signature with the received data or image"}, said processing including storing the specimen description in association with the facility identifier in a network accessible data storage device {See JAMROGA, C10:L43-52, wherein this reads over "the central database can be comprised of one or more databases located remotely from each other"};

storing specimen handling data that specifies a clinic laboratory specimen handling rating {See Cusack, C5:L50-58, wherein this reads over "[t]he registration information also requires entry of one of a CLIA number, an FDA registration number or a medical license number. (The CLIA number refers to a state license issued to laboratories under the Clinical Lab Improvement Act") Of each of multiples specimen collection facilities {See JAMROGA, C11:L42-53, wherein this reads over "[t]he proxy server 32 layer preferably interfaces with DICOM compliant medical radiology modalities 62 located on the participant's network 34, for the purpose of either manually or automatically providing a communication and storage device for transmitting and storing various DICOM or non-DICOM compliant data and images generated from such modalities"};

determining a correlation between the specimen image content and the clinical laboratory specimen handling ratings of each of the multiple specimen collection facilities {See JAMROGA, C11:42-54, wherein this reads over "various DICOM or non-DICOM compliant data and images"; and C11:L65-C12:L10};

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selecting one or more of the multiple specimen collection facilities to send the specimen report in accordance with said determined correlation {See JAMROMGA, C11:L48-53, wherein this reads over "[t]he proxy server 32 layer includes and encompasses all necessary DICOM specific communication protocols . . . "; and

sending the specimen report to the selected one or more of the multiple specimen collection facilities {See JAMROGA, C13:L66-C14:L3, wherein this reads over "[o]nce the query is processed, the requested information is transmitted 98 to the proxy server 32 over communication link 20 and re-stored on the RAID storage 48 where the information is then automatically transmitted 107 to the participant institution"}.

While Jamroga et al fails to expressly disclose the specification of a clinic laboratory specimen handling rating, Cusack et al discloses the use of CLIA number which identifies whether a specimen collection facility is licensed under the Clinical Lab Improvement Act. Accordingly, it would have been obvious to one of ordinary skill in the art that the CLIA number (i.e. the clinic laboratory specimen handling number) may be stored to identify eligible facilities in the management of specimen data reporting. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above invention suggested by Jamroga et al by combining it with the invention disclosed by Cusack et al. One of ordinary skill in the art would have been motivated to make such a modification such that a CLIA number may be used in the management of specimen data report among specimen collection facilities such that only licensed facilities would be able to retrieveing specimen reports.

11. **As per dependent claims 46 and 47**, JAMROGA, in combination with CUSACK, discloses:

The method of claim 17, wherein said determining a correlation is performed using a rule-based algorithm, an inference engine, or a neural network {See JAMROGA, Figure 1}.

12. **Claims 18, 20-21, 31, and 34** are rejected under 35 U.S.C. 103(a) as being unpatentable over JAMROGA, in view of CUSACK, and in further view of Kaltanji (USPGPUB 2004/0165791, hereinafter referred to as KALTANJI), filed on 21 February 2003, and published on 26 August 2004.

JAMROGA AND CUSACK teach all the limitations of claims 17 and 30 for the reasons stated above.

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JAMROGA AND CUSACK differ from the claimed invention in that they fail to specifically disclose the use of file directories having directory names corresponding to a facility identifier (claims 18 and 31).

JAMROGA AND CUSACK differ from the claimed invention in that they fail to specifically disclose the representation of file directories as graphical user interface folders (claims 19 and 32).

JAMROGA AND CUSACK differ from the claimed invention in that they fail to specifically disclose the storage of specimen descriptors in association with the facility identifiers (claims 20 and 33).

JAMROGA AND CUSACK differ from the claimed invention in that they fail to specifically disclose the copying of digital images files into a digital image library directory (claims 21 and 34).

13. **As per dependent claims 18 and 31**, JAMROGA, in combination with CUSACK and KALTANJI, discloses:

The method of claim 17, wherein said storing the specimen description in association with the facility identifier comprises copying the specimen description into one or more file directories having directory names corresponding to the facility identifier {See KALTANJI, [0033], wherein this reads over "the directory name format of each sub-directory will include a unique patient identifier for that particular patient, which can include any number of indicia"}.

KALTANJI discloses a method wherein the directory name format may include any number of indicia which reflect a certain attribute or property of the data stored therein. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above invention suggested by JAMROGA by combining it with the invention disclosed by KALTANJI.

One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA could have file directories which stored specimen description data according to the facility identifiers.

14. **As per dependent claim 20**, JAMROGA, in combination with CUSACK and KALTANJI, discloses:

The method of claim 17, wherein said storing the specimen description in association with the facility identifier comprises associating the specimen description with the facility identifier in one or more database records {See KALTANJI, [0036], wherein this reads over "[t]he file name format of each dental image file will typically include a number of indicia such as a patient identifier, a file creation date, a file creation time, a modification date, a description of the source from which the image was derived, and an image description"}.

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KALTANJI discloses a method wherein the file name format of the images may include "a description of the source from which the image was derived." Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above invention suggested by JAMROGA by combining it with the invention disclosed by KALTANJI.

One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA would comprise of the database records which identified the source facility identifier by associating the specimen description with a facility identifier.

15. **As per dependent claims 21 and 34**, JAMROGA, in combination with CUSACK and KALTANJI, discloses:

The method of claim 18, wherein the specimen image content is contained in one or more digital image files, said copying the specimen description into one or more file directories further comprising copying the one or more digital image files into a digital image library directory, the digital image library directory having a directory name corresponding to the facility identifier {See JAMROGA, C10:L43-52, wherein this reads over "the central database can be comprised of one or more databases located remotely from each other, each acting as a redundant back-up database for the other for purposes of storing data and images for retrieval in case of disaster or destruction of the other database"}.

KALTJANI discloses a method for have more than one database for the purposes of "a redundant back-up database." Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above invention suggested by JAMROGA by combining it with the invention disclosed by KALTANJI.

One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA would further comprise of a digital image library directory wherein digital images are copied into.

16. **Claim 22, 24, 35, and 37** are rejected under 35 U.S.C. 103(a) as being unpatentable over JAMROGA, in view CUSACK, and in further view of Imai et al (U.S. Patent No. 5,987,510, hereinafter referred to as IMAI), filed on 8 November 1996, and issued on 16 November 1999.

JAMROGA and CUSACK teach all the limitations of claims 17 and 30 for the reasons stated above.

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JAMROGA and CUSACK differ from the claimed invention in that they fail to specifically disclose the processing of specimen reports in order of their priority levels (claims 22, 24, 35, and 37).

17. **As per dependent claims 22 and 35**, JAMROGA, in combination with CUSACK and IMAI, discloses:

The method of claim 17, wherein the received specimen report further includes a priority level indicator {See IMAI, C10:L36-37, wherein this reads over "the individual data of each file can include a file size, a priority level, etc."} selected from among priority level indicia representing levels of urgency associated with the specimen report, said method further comprising processing the received specimen report in accordance with the priority level indicator {See IMAI, C10:L52-55, wherein this reads over "the processing is sequentially carried out for the sorted files in the priority level order"}, said processing the received specimen report in accordance with the priority level indicator comprising triggering a user alert signal in accordance with the level of urgency represented by the priority level indicator included with the specimen report {See PAYNE, C30:L9-13, wherein this reads over "[w]hen the alert message is received . . . an animated visual and/or audio notification is triggered"}.

IMAI discloses a method wherein the files can also include a priority level and processed accordingly. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above invention suggested by JAMROGA by combining it with the invention disclosed by IMAI.

One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA would allow for specimen reports to be processed in order of their priority levels.

18. **As per dependent claim 24**, JAMROGA, in combination with CUSACK and IMAI, discloses:

The method of claim 22, wherein said processing the received specimen report in accordance with the priority level indicator comprises storing the specimen report in association with the priority level indicator in a network accessible data storage device {See IMAI, C10:L36-37, wherein this reads over "the individual data of each file can include a file size, a priority level, etc."}.

IMAI discloses a method wherein the files can also include a priority level and processed accordingly. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above invention suggested by JAMROGA by combining it with the invention disclosed by IMAI.

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One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA would allow for specimen reports to be processed in order of their priority levels.

19. **As per dependent claim 37**, JAMROGA, in combination with CUSACK and IMAI, discloses:

The method of claim 24, wherein said storing the specimen report in association with the priority level indicator comprises associating the priority level indicator with the specimen report {See IMAI, C10:L36-37, wherein this reads over "the individual data of each file can include a file size, a priority level, etc."} in one or more database records.

IMAI discloses a method wherein the files can also include a priority level and processed accordingly. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above invention suggested by JAMROGA by combining it with the invention disclosed by IMAI.

One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA would allow for specimen reports to be processed in order of their priority levels.

20. **Claims 27 and 39** are rejected under 35 U.S.C. 103(a) as being unpatentable over JAMROGA, in view of CUSACK, and in further view of IMAI, and in further view of Ecker et al (USPGPUB 2003/0082539, hereinafter referred to as ECKER), filed on 26 June 2001, and published on 1 May 2003.

JAMROGA and CUSACK teach all the limitations of claims 17 and 30 for the reasons stated above.

JAMROGA and CUSACK differ from the claimed invention in that they fail to specifically disclose the determination and assignment of epidemiological threat levels for specimens (claims 27 and 39).

21. **As per dependent claims 27 and 39**, JAMROGA, in combination with CUSACK, IMAI and ECKER, discloses:

The method of claim 17, further comprising:

determining an epidemiological threat level in accordance with the specimen description {See ECKER, [0087], wherein this reads over "[c]omparison of newly observed bioagents to known bioagents is also possible, for examination of threat level, by comparing their BCS to those of known organisms"}; and

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assigning a priority level designation to the received specimen report in accordance with the determined epidemiological threat level {See IMAI, C10:L36-37, wherein this reads over "the individual data of each file can include a file size, a priority level, etc."}.

ECKER discloses a method wherein epidemiological threat levels may be assigned in accordance with the specimen description by comparing the specimens to other known bioagents. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above invention suggested by JAMROGA by combining it with the inventions disclosed by IMAI and ECKER.

One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA would further comprise of assigning certain priority levels to specimens in accordance with the epidemiological threat level so that such specimens may be processed according to their threat levels.

22. **Claims 28-29 and 40-41** are rejected under 35 U.S.C. 103(a) as being unpatentable over JAMROGA, in view of IMAI and ECKER, and in further view of Payne et al (U.S. Patent No. 6,021,433, hereinafter referred to as PAYNE), filed on 24 January 1997, and issued on 1 February 2000.

JAMROGA and CUSACK teach all the limitations of claims 17 and 30 for the reasons stated above.

JAMROGA AND CUSACK differ from the claimed invention in that they fail to specifically disclose the determination and assignment of epidemiological threat levels for specimens (claims 28-29 and 40-41).

23. **As per dependent claims 28 and 40**, JAMROGA, in combination with CUSACK, IMAI, ECKER, and PAYNE, discloses:

The method of claim 27, further comprising delivering an alert message to at least one other specimen collection facility, wherein the alert message includes the specimen description associated with the facility identifier and the priority level designation {See PAYNE, C30:L17-24, wherein this reads over "the alert is not limited to the provider ID code number and name. Rather, the E-mail alert could include a header, whole message, etc"}.

PAYNE discloses a method wherein an alert message is sent include a variety of related information. It would have been obvious to one of ordinary skill in the art to have the alert message include a description of the specimen and the priority level. Therefore, it would have been obvious to

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one of ordinary skill in the art at the time the invention was made to modify the above invention suggested by JAMROGA by combining it with the inventions disclosed by IMAI, ECKER and PAYNE.

One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA would further disclose to a user the priority level and a description of the specimen in an alert message.

24. **As per dependent claims 29 and 41**, JAMROGA, in combination with CUSACK, IMAI, ECKER, and PAYNE, discloses:

The method of claim 28, further comprising, responsive to said delivering an alert message to at least one other specimen collection facility, storing an alert message status record {See PAYNE, C30:L17-24, wherein this reads over "the date and time the alert was received"}.

PAYNE discloses a method wherein an alert message may be delivered to another specimen collection facility, and an alert message status record is stored (i.e. the date and time the alert was received may be stored). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above invention suggested by JAMROGA by combining it with the inventions disclosed by IMAI and PAYNE.

One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA would further comprise of delivering an alert message to other specimen collection facilities and storing an alert message status record.

Response to Arguments

25. Applicant's arguments with respect to claims 17 and 30 have been considered but are moot in view of the new ground(s) of rejection.

Additionally, regarding Applicant attempt at distinguishing "Applicants' claimed processing of the image content itself from Jamroga's processing of the DICOM file format and transport protocol," it is noted that Jamroga discloses the transmission of both data and images between a central database and a participant institution. Accordingly, while Applicant may have distinguished specimen image data from

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the actual specimen image content, it is noted that Jamroga continues to fully read upon the invention as claimed.

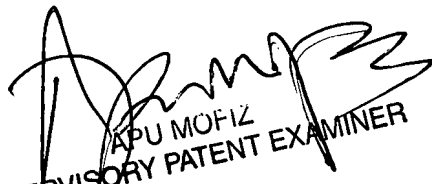
Conclusion

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Kim whose telephone number is (571) 272-2737. The examiner can normally be reached on M-F, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Apu Mofiz can be reached on (571) 272-4080. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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